

REMARKS/ARGUMENTS

Claims 1 - 38 and 45 - 48 are pending. Claim 49 is new, and is supported by claim 35. Claims 35 and 48 are amended. Claim 35 is amended to remove the subject matter of new claim 49. No new matter is introduced by way of these amendments.

As amended, 43 total claims and 10 independent claims are pending. In view of the claims originally filed, no additional fee is due.

- I. *Claims 1-38 and 45-48 are rejected under 35 USC 112, first paragraph, for not being enabling for other than the treatment of breast cancer with CCI-779 and an aromatase inhibitor (claim 6).*

Applicants respectfully traverse this rejection. As a preliminary matter, Applicants note that claim 6, directed to breast cancer, was inadvertently included in the Examiner's listing of rejected claims. The Examiner's remarks at page 3 of the Action acknowledge enablement for the treatment of breast cancer. Further, Applicants note that claim 35, directed to a method of treating an estrogen receptor positive carcinoma of the breast or ovary with CCI-779 and an aromatase inhibitor, was also acknowledged by the Examiner to be enabled at page 3 of the Office Action dated January 15, 2008. New claim 49 should similarly be considered to satisfy the enablement requirement.

Applicants disagree that "the [Pilosi] reference is concise and proper" in supporting the present enablement rejection. Pilosi¹ does not address predictability with regard to the treatment of neoplasms generally, as Pilosi is limited to discussion of a rare tumor type (seven total cases)², rather than neoplasms generally. While the Examiner's assertion that "[t]he pertinent art still deems neoplastic conditions/solid

¹ Giuseppe Pelosi M.D., *et al.*, Mod. Pathol. 2001:14(5):521-526.

² *Id.* at Abstract.

tumors as unpredictable in their clinical behavior"³ is arguably 'concise', it is not 'proper' to extend the opinion of Pilosi's authors to neoplasms generally. Pilosi does not describe the study of neoplasms generally, and thus one of skill in the art would not accept its overreaching and generalized opinion as fact. Accordingly, Pilosi does not serve to enlighten the enablement inquiry with respect to the pending claims.

The test for enablement is whether one of skill in the art "can make and use the invention without undue experimentation."⁴

Of the specific factors recited in In re Wands⁵ for consideration in determining whether undue experimentation is required, the relative skill of those in the art is mentioned by the Examiner only in regard to the Board's decision in Ex parte Forman⁶. Unlike Ex parte Forman, where guidance was not provided as to how to obtain any of the claimed living attenuated oral vaccines, the present specification demonstrates a method of treating a neoplasm with a combination of CCI-779 and an aromatase inhibitor. The present specification also provides guidance as to a broad array of neoplasms for which the claimed methods, combinations, and compositions are useful.

In view of the guidance within the specification as a whole, one of skill in the art in treating neoplasms (a high level of skill) would be able to practice the full scope of the claims without undue experimentation.

³ January 15, 2008 Office Action at page 6.

⁴ See, e.g., MPEP §2164.01.

⁵ 8 USPQ2d 1400 at 1404 (CAFC 1988).

⁶ 230 USPQ 546 (BPAI 1986).

- II. *Claims 1-41 and 45 – 48 have been rejected under 35 USC 102(e) as being anticipated by Dukart et al, US Published Patent Application 2003/0008923 A1 (Dukart).*

Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.⁷

Claim 1 recites "[a] method of treating a neoplasm in a mammal in need thereof by providing to said mammal an effective amount of a combination consisting of CCI-779 and an aromatase inhibitor." The claim requires a closed combination of CCI-779 and an aromatase inhibitor. Accordingly, in order to be anticipated, Dukart must describe 'each and every element' of claim 1, *i.e.*, a closed combination of CCI-779 and an aromatase inhibitor.

Nowhere in Dukart is there a teaching of a combination *consisting of* CCI-779 and an aromatase inhibitor. Addressing the Examiner's specific allegations at page 7 of the May 30, 2008 Office Action, Dukart does describe at paragraph 0064 that

this invention also covers the use of the mTOR inhibitor/alkylating agent *combination used in conjunction with* other chemotherapeutic agents, such as . . . hormonal agents (*i.e.*, . . . letrozole) . . .

However, with respect to claim 1, a closed *combination* of CCI-779 (an mTOR inhibitor) and an aromatase inhibitor is not described. As is evidenced by the above passage, the claims and the remaining description of Dukart, inclusion of an *antineoplastic alkylating agent* with the mTOR inhibitor *was* described throughout, which antineoplastic alkylating agent is *excluded* by the language of the pending claims.

For the above reasons, Dukart [only available for application in a novelty rejection under 35 USC 102(e)] does not affect the novelty of the pending claims.

⁷ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2, USPQ2d 1051, 1053 (Fed. Cir. 1987).


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Applicants note that, even assuming it was merely applied as a reference under 35 USC 103(a), Dukart would not preclude patentability, because the subject matter of Dukart and the claimed invention were, at the time the claimed invention was made, owned by Wyeth or subject to an obligation of assignment to Wyeth [35 USC 103(c)(1)].

In view of the above, reconsideration and withdrawal of this rejection is requested.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application to Deposit Account Number 08-3040.

Respectfully submitted,
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